1.0 PURPOSE

The purpose of this policy is to provide guidance as to the requirements for the development of Informed Consent for Division of AIDS (DAIDS) funded and/or sponsored human subject clinical research.

This policy is intended to ensure consistent and acceptable standards for adherence to Title 45 Part 46 of the Code of Federal Regulations (45 CFR 46) in addition to all DAIDS/Department of Health and Human Services (DHHS) guidance or directives as well as other applicable local, federal, and international laws and regulations regarding the process and documentation of informed consent.

2.0 SCOPE

This policy applies to all human subjects clinical research requiring an informed consent and that is funded and/or sponsored by the Division of AIDS.

3.0 BACKGROUND

All National Institute of Allergy and Infectious Diseases (NIAID) supported research involving human subjects must be consistent with and adhere to 45 CFR 46, any DAIDS/DHHS guidance or directives, as well as other applicable local, federal, and international laws and regulations regarding the content, process, and documentation for obtaining informed consent.

4.0 DEFINITIONS

DAIDS funded – DAIDS is providing financial support for the clinical trial.

DAIDS sponsored – DAIDS is responsible for the management (including submission of the Investigational New Drug Application (IND) to the FDA, and initiation of the study), and oversight for the clinical trial.

Full Regulatory Review – The final review of the protocol, including the sample informed consent(s), by the Regulatory Affairs Branch (RAB) prior to Medical Officer sign off and distribution to the sites.

Informed Consent Form (ICF) – A document that provides information to a prospective research subject regarding the purpose, procedure, and potential risks and benefits as outlined 45 CFR 46.

Institutional Review Board/Ethics Committee (IRB/EC) – An independent committee of physicians, statisticians, researchers, community advocates, and others that ensures a clinical study is ethical, and the rights of clinical participants are protected.

Scientific Review Committee (SRC) – A reviewing body instituted by DAIDS to review the concepts and protocols developed by various programs within DAIDS.

For additional definitions see DAIDS Glossary.

5.0 RESPONSIBILITIES

- It is the responsibility of the DAIDS Medical Officer/Program Officer (MO/PO) to provide a preliminary assessment of the accuracy and completeness of the Informed Consent document(s) prior to SRC review.

- It is the responsibility of the DAIDS Regulatory Affairs Branch (RAB) Human Subjects Protection (HSP) Team to provide oversight and review of the submitted IC document(s) at the time of SRC review and, if applicable, Full Regulatory Review.

- For clinical studies not undergoing SRC review, the DAIDS MO/PO is responsible for providing oversight and review of IC documents submitted to DAIDS, and for ensuring that the IRB/IEC has reviewed and approved the ICF reflecting the most current version of the protocol.

6.0 POLICY

Informed Consent Forms must include all basic elements and additional elements as appropriate as described in 45 CFR 46 subsection 116 [see Appendix A, Office for Human Research Protections (OHRP) Informed Consent checklist], the DHHS policy on HIV testing and counseling (see Appendix B), as well as any DAIDS-specific guidance or requirements listed below.

Breast-Feeding: Because there may be potential risk to the newborn, a statement about breast feeding must be included in the ICF for clinical trials that enroll women of child bearing potential. This statement must specify that it is unknown if the study drug(s) pass through breast milk and whether this may produce bad effects in the infant. If applicable, the ICF should also state that it is unknown if taking study drugs will reduce the risk of passing HIV to the baby while breast feeding.

Study Product Risk List: DAIDS maintains a pharmaceutical manufacturer approved list of expected risks associated with some agents that are used in DAIDS sponsored clinical trials. DAIDS requires the available risk list be included in the ICF, and given to subjects before signing the ICF. These lists can be found at http://rcc.tech-res-intl.com/drugrisklist.htm

Study Related Test Results: The subject must be informed if and/or when the results of any required study testing will be made available to them.

Storage of Biological Specimens: There must be a description in the ICF concerning the storage of biological specimens. It must reflect if and how these specimens may be used in future study-related and/or unspecified future research. Subjects should also be informed if the storage of biological specimens for future research is a requirement for study participation. If not, subjects should be given the option to refuse to allow any storage of biological specimens. Furthermore, the ICF should clarify if these biological specimens will be shipped and/or stored outside of the country where they were collected.

Compensation for Study Related Injury: The ICF must state that the U.S. National Institutes of Health (NIH) does not have a mechanism to provide direct compensation for research related injury. (If a mechanism to compensate for study related injury is available, this should be explained in the ICF.)

All documents that will be used in the informed consent process should be at an appropriate level of understanding for the intended study population. Investigators must seek guidance from the local IRB/EC, and local regulatory authorities regarding waiver of consent, oral informed consent process for participants who can not read or write, assent procedures for children, and other vulnerable populations as appropriate.

7.0 REFERENCES

U.S. Code of Federal Regulations 45 CFR 46
http://www.gpoaccess.gov/ecfr/

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guideline (ICH), E6, Section 4.8
http://www.ich.org

Office for Human Research Protection Guidance
http://www.hhs.gov/ohrp/policy/

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at:

NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

The signed original is maintained in the OPCRO policy office.

10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
1.0	14 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

Appendix 1: OHRP Informed Consent Checklist
http://www.hhs.gov/ohrp/humansubjects/assurance/consentckls.htm

Appendix 2: DHHS Policy on HIV Testing and Counseling
http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc88jun.htm

12.0 APPROVAL

	Signature	Program/Branch	Date
Authorized By:	Richard Hafner Richard Hafner, MD Director	Office for Policy in Clinical Research Operations	July 14, 2006